

Food and Drug Administration, HHS

§ 522.23

- 522.1350 Melatonin implant.
 522.1362 Melarsomine dihydrochloride for injection.
 522.1367 Meloxicam.
 522.1372 Mepivacaine.
 522.1380 Methocarbamol injection.
 522.1410 Sterile methylprednisolone acetate suspension.
 522.1450 Moxidectin solution.
 522.1451 Moxidectin for suspension.
 522.1452 Nalorphine hydrochloride injection.
 522.1462 Naloxone hydrochloride injection.
 522.1465 Naltrexone hydrochloride injection.
 522.1468 Naproxen for injection.
 522.1484 Neomycin sulfate sterile solution.
 522.1503 Neostigmine methylsulfate injection.
 522.1610 Oleate sodium solution.
 522.1620 Orgotein for injection.
 522.1642 Oxymorphone hydrochloride injection.
 522.1660 Oxytetracycline injectable dosage forms.
 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.
 522.1660b Oxytetracycline solution, 300 milligrams/milliliter.
 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.
 522.1662a Oxytetracycline hydrochloride injection.
 522.1662b Oxytetracycline hydrochloride with lidocaine injection.
 522.1680 Oxytocin injection.
 522.1696 Penicillin G procaine implantation and injectable dosage forms.
 522.1696a Penicillin G benzathine and penicillin G procaine suspension.
 522.1696b Penicillin G procaine aqueous suspension.
 522.1696c Penicillin G procaine in oil.
 522.1698 Pentazocine lactate injection.
 522.1704 Sodium pentobarbital injection.
 522.1720 Phenylbutazone injection.
 522.1820 Pituitary luteinizing hormone for injection.
 522.1850 Polysulfated glycosaminoglycan.
 522.1862 Sterile pralidoxime chloride.
 522.1870 Praziquantel injectable solution.
 522.1881 Sterile prednisolone acetate aqueous suspension.
 522.1883 Prednisolone sodium phosphate.
 522.1884 Prednisolone sodium succinate injection.
 522.1885 Prednisolone tertiary butylacetate suspension.
 522.1890 Sterile prednisone suspension.
 522.1920 Prochlorperazine, isopropamide for injection.
 522.1940 Progesterone and estradiol benzoate.
 522.1962 Promazine hydrochloride.
 522.2002 Propiopromazine hydrochloride injection.
 522.2005 Propofol injection.
 522.2012 Prostalene solution.
 522.2063 Pyrilamine maleate injection.
 522.2076 Romifidine.
 522.2100 Selenium, vitamin E injection.
 522.2112 Sometribove zinc suspension.
 522.2120 Spectinomycin dihydrochloride injection.
 522.2121 Spectinomycin sulfate.
 522.2150 Stanozolol sterile suspension.
 522.2200 Sulfachlorpyridazine.
 522.2220 Sulfadimethoxine injection.
 522.2240 Sulfaethoxypyridazine.
 522.2260 Sulfamethazine injectable solution.
 522.2340 Sulfomyxin.
 522.2404 Thialbarbitone sodium for injection.
 522.2424 Sodium thiamylal for injection.
 522.2444 Sodium thiopental implantation or injectable dosage forms.
 522.2444a Sodium thiopental for injection.
 522.2444b Sodium thiopental, sodium pentobarbital for injection.
 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.
 522.2471 Tilmicosin.
 522.2474 Tolazoline hydrochloride injection.
 522.2476 Trenbolone acetate.
 522.2477 Trenbolone acetate and estradiol.
 522.2478 Trenbolone acetate and estradiol benzoate.
 522.2483 Sterile triamcinolone acetonide suspension.
 522.2582 Triflupromazine hydrochloride injection.
 522.2610 Trimethoprim and sulfadiazine.
 522.2615 Tripeleminamine hydrochloride injection.
 522.2630 Tulathromycin.
 522.2640 Tylosin.
 522.2662 Xylazine.
 522.2670 Yohimbine injectable.
 522.2680 Zeranor.
 522.2690 Zinc gluconate.
- AUTHORITY: 21 U.S.C. 360b.
- SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.
- § 522.23 Acepromazine maleate injection.**
- (a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of acepromazine maleate.
- (b) *Conditions of use.* See No. 000010, 000856 and 059130 in § 510.600(c) of this chapter for use in dogs, cats, and horses as follows:
- (1) *Indications for use.* It is used in dogs, cats, and horses as a tranquilizer.
- (2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.
- (c) *Conditions of use.* See No. 000010 in § 510.600(c) of this chapter for use in dogs as follows:

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(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight.

(3) *Limitations.* The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 43831, Sept. 1, 1981, as amended at 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 68 FR 33856, June 6, 2003; 69 FR 33840, June 17, 2004]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.¹

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 522.46 Alfaprostol.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of alfaprostol.

(b) *Sponsor.* No. 055882 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses as follows:

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

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(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 43300, Sept. 23, 1983, as amended at 53 FR 40057, Oct. 13, 1988]

§ 522.56 Amikacin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use.*—(1) *Amount.* 5 milligrams per pound of body weight twice daily.

(2) *Indications for use.* The drug is used in dogs for treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(3) *Limitations.* The drug is administered intramuscularly or subcutaneously. Treat dogs with skin and soft tissue infections for a minimum of 7 days and those with genitourinary infections for 7 to 21 days or until culture is negative and asymptomatic. If no response is observed after 3 days of treatment, therapy should be discontinued and the case re-evaluated. Maximum duration of therapy should not exceed 30 days. Systemic aminoglycoside therapy is contraindicated in dogs with seriously impaired renal function. Not for use in breeding dogs as reproductive studies have not been conducted. Use with extreme caution in dogs in which hearing